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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,915	07/22/2003	D. Russell Pflueger	D-3077	7109

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STOUT, UXA, BUYAN & MULLINS LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER	
RAGONESE, ANDREA M	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,915	PFLUEGER ET AL.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *12,39 and 62-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-38 and 40-61* is/are rejected.

7)☒ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species IV, **claims 1-11, 13-38** and **40-61**, as shown in Figures 7 and 26, in the reply filed on November 8, 2004 is acknowledged.

2. **Claims 12, 39** and **62-65** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 8, 2004.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

> The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
>
> The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the use of improper sentence structure. The abstract should only contain complete sentences, not run-on sentences as it currently does. Correction is required. See MPEP § 608.01(b).

Claim Objections

5. **Claim 38** is objected to because of the following informalities: the Examiner believes **claim 38** should depend from **claim 36** (not **claim 34** as it currently does). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 1-11, 13-18** and **55** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **claim 1**, the phrase "the appliance being further effective, when so placed..." renders the claim vague and indefinite because the metes and bounds of the claim are not clearly defined.

Claim 55 recites the limitation "The method" in line 1. There is insufficient antecedent basis for this limitation in the claim. The Examiner believes that **claim 55** should depend from **claim 52** (not **claim 50**) as it currently does.

8. Any rejections in this Office action have been made by applying any pertinent prior art in the field to the merits of the claimed invention as best understood by the Examiner.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. **Claims 1-11, 13-38** and **40-61** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicant recites "the human or animal." This clause (and other similar clauses) appears to

positively recite a human being or an animal. Although the recitation of "the human or animal" is in an inferential clause, the use of "the" to refer to a living creature raises the possibility that Applicant is positively reciting a human being or an animal. Accordingly, **claims 1-11, 13-38** and **40-61** are considered to be directed to non-statutory subject matter. 1077 OG 24 (April 21, 1987).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. **Claims 1-5, 7-11, 13, 14, 16-29, 31-38, 40-51** and **56-61** are rejected under 35 U.S.C. 102(b) as being anticipated by Conrad et al. (US 6,250,307 B1).

Regarding **claim 1**, Conrad et al. discloses an appliance **20** sized and structured to be fully capable of being placed in a given position in the oropharyngeal region, and fully capable of being effective in treating at least one of sleep apnea and snoring, and fully capable of being further effective, when so placed, to provide at least one additional benefit relative to a device sized and structured for placement in a position in

a human or animal other than in the given position in the oropharyngeal region when the device **30** is placed in the given position in the oropharyngeal region.

Regarding **claim 2**, the appliance **20** is sized so that, when so placed in the given position in the oropharyngeal region, the appliance is fully capable of being located substantially entirely in the oropharyngeal region.

Regarding **claim 3**, wherein the at least one benefit comprises the fully capability of producing an enhanced compliance of the appliance **20** with the functioning of at least one of the oropharyngeal region and the epiglottis.

Regarding **claim 4**, wherein the at least one benefit comprises an enhanced ability of the appliance **20** to be fully capable of providing support against collapse of the oropharyngeal region during sleep, and to be fully capable to allow closure of an airway in the oropharyngeal region during swallowing.

Regarding **claim 5**, wherein the at least one benefit comprises an enhanced ability of the appliance **20** to be tolerated by a human or animal in the given position.

Regarding **claim 7**, wherein the appliance **20** comprises a member defining a substantially C-shaped configuration, as shown in Figure 15.

Regarding **claim 8**, wherein the appliance **20**, when located outside a human or animal, comprises a member that is fully capable of being substantially flat.

Regarding **claim 9**, wherein the applicance **20** is sized and structured to be fully capable to permit substantially natural movement of the epiglottis when the applicance **20** is located in the given position in the oropharyngeal region of a human or animal.

Regarding **claim 10**, wherein the appliance **20** includes spaced apart, radiused end portions.

Regarding **claim 11**, wherein the appliance **20** includes end portions and is further sized and structured, when the appliance **20** is located in the given position, to be fully capable of being positioned against a portion of a posterior wall of the oropharyngeal region with the end portions being spaced apart anteriorly of the posterior wall.

Regarding **claim 13**, wherein the appliance **20** comprises a super-elastic material (column 5, lines 51-53).

Regarding **claim 14**, wherein the appliance **20** comprises Nitinol (column 5, lines 67 through column 6, line 1).

Regarding **claim 16**, wherein the applicance **20** comprises a cuff-shaped member.

Regarding **claim 17**, wherein the cuff-shaped member includes spaced apart end portions.

Regarding **claim 18**, wherein the cuff shaped member is sized and structured to be fully capable of being positioned against a portion of a posterior wall of the oropharyngeal region with the end portions being spaced apart by a portion of an anterior wall of the oropharyngeal region.

Regarding **claim 19**, Conrad et al. discloses an appliance **30** sized and structured to be fully capable of being placed, at least partially submucosally, within the pharyngeal region of a human or animal and to be effective, when so placed, fully

capable of maintaining patency of the pharyngeal region during natural sleep of a human or animal.

Regarding **claim 20**, wherein the appliance **30** is structured to be fully capable of being effective in treating at least one of sleep apnea and snoring.

Regarding **claim 21**, wherein the appliance **30** is structured to be fully capable of being effective in treating sleep apnea.

Regarding **claim 22**, wherein the appliance **30** is structured to be fully capable of being placed in an oropharyngeal region.

Regarding **claim 23**, wherein the appliance **30** is sized to be fully capable of being placed at least partially circumscribing an interior hollow passage defined by the pharyngeal region.

Regarding **claim 24**, wherein the appliance **30** is sized to be fully capable of being placed at least partially circumscribing an interior hollow passage defined by the oroparyngeal region.

Regarding **claim 25**, wherein the appliance **30** is sized to be fully capable of being placed circumscribing an interior hollow passage defined by the pharyngeal region.

Regarding **claim 26**, wherein the appliance **30** is sized to be fully capable of being placed circumscribing an interior hollow passage defined by the oropharyngeal region.

Regarding **claim 27**, wherein the appliance **30** comprises at least one elongated member.

Regarding **claim 28**, wherein the appliance **30** comprises a single elongated member.

Regarding **claim 29**, wherein the appliance **30** comprises at least one elongated member having a polygonal cross-section.

Regarding **claim 31**, wherein the appliance **30** is structured to be fully capable of being substantially entirely submucosally placed within the pharyngeal region.

Regarding **claim 32**, wherein the pharyngeal region has right and left lateral walls, and the appliance **30** is structured to be fully capable of being implanted, at least partially submucosally, within the pharyngeal region, such that the appliance **30** at least partially traverses the right and left lateral walls.

Regarding **claim 33**, wherein the pharyngeal region has right and left lateral walls, and the appliance **30** is structured to be fully capable of being implanted, at least substantially entirely submucosally, within the pharyngeal region, such that the appliance **30** at least partially traverses the right and left lateral walls.

Regarding **claim 34**, wherein the appliance **30** comprises a super-elastic material.

Regarding **claim 35**, wherein the appliance **30** comprises Nitinol.

Regarding **claim 36**, Conrad et al. discloses an appliance **20** sized and structured to be fully capable of being placed in a position in the oropharyngeal region in proximity to the epiglottis, other than to facilitate a surgical procedure, and to be fully capable of being effective in treating at least one of sleep apnea and snoring.

Regarding **claim 37**, wherein the appliance **20** is structured to be fully capable of being at least partially submucosally placed in the oropharyngeal region.

Regarding **claim 38**, wherein the appliance **20** is structured to be fully capable of being substantially entirely submucosally placed in the oropharyngeal region.

Regarding **claim 40**, wherein the appliance **20** is structured to be fully capable to cause tissue stiffening when the appliance **20** is placed in the position in the oropharyngeal region.

Regarding **claim 41**, wherein the oropharyngeal region has lateral walls and the appliance **20** is structured, when so placed in the position, to be fully capable of supporting lateral walls of the oropharyngeal region against collapse during natural sleep, and to be fully capable to allow closure of an airway in the oropharyngeal region during swallowing.

Regarding **claim 42**, wherein the appliance **20** comprises a member defining a substantially C-shaped configuration.

Regarding **claim 43**, wherein the appliance **20**, when located outside a human or animal, comprises a member, which is fully capable of being substantially flat.

Regarding **claim 44**, wherein the appliance **20** is sized to be fully capable of permitting substantially natural movement of the epiglottis when the apparatus **20** is located in the position.

Regarding **claim 45**, wherein the appliance **20** includes spaced apart, radiused end portions.

Regarding **claim 46**, wherein the appliance **20** includes spaced apart end portions and is further sized and structured to be fully capable of being positioned against a portion of a posterior wall of the oropharyngeal region with the end portions spaced apart by a portion of an anterior wall of the oropharyngeal region.

Regarding **claim 47**, wherein the appliance **20** has a resiliency and flexibility to be fully capable of allowing natural functioning of the oropharyngeal region during swallowing and a hoop strength effective to be fully capable of supporting the oropharyngeal region against collapse during natural sleep.

Regarding **claim 48**, wherein the appliance **20** comprises a super-elastic material.

Regarding **claim 49**, wherein the appliance **20** comprises Nitinol.

Regarding **claim 50**, Conrad et al. discloses an appliance **30** sized and structured to be fully capable of being placed in a position in the oropharyngeal region in proximity to the epiglottis, other than to facilitate a surgical procedure, and being fully capable of being effective in treating at least one of sleep apnea and snoring, the appliance **30** being structured, when placed in the position in the oropharyngeal region, to be fully capable of supporting the lateral walls of the oropharyngeal region against collapse during the time a human or animal is naturally sleeping.

Regarding **claim 51**, wherein the appliance **30** is sized so that, when placed in the position in the oropharyngeal region, the appliance is fully capable of being located substantially entirely in the oropharyngeal region.

Regarding **claim 56**, Conrad et al. discloses an appliance **30** comprising a body portion and end portions spaced apart by the body portion, the appliance being structured to be fully capable of taking on a deployed configuration when located within the oropharyngeal region, such that the end portions are spaced apart from each other anteriorly of a posterior wall of the oropharyngeal region, and the appliance **30** being further structured to be fully capable of exerting a force on the lateral walls of the oropharyngeal region, when the appliance **30** is in the deployed configuration within the oropharyngeal region, in order to cause the oropharyngeal region to be maintained substantially unobstructed.

Regarding **claim 57**, wherein the end portions are coupled together only through the body portion.

Regarding **claim 58**, wherein the appliance **30** is structured to be fully capable of forming a relatively flat configuration when the appliance **30** is at rest outside a human or animal.

Regarding **claim 59**, Doshi discloses a method inherent in the use of an appliance **20**, the method comprising the steps of providing a member in a substantially flat or precurved configuration, the member having a body portion and end portions spaced apart by the body portion; and implanting the member, at least partially submucosally, within the pharyngeal region.

Regarding **claim 60**, wherein the pharyngeal region has right and left lateral walls, and the member is fully capable of being effective to provide a substantially constant force against at least a portion of each of the right and left lateral walls.

Regarding **claim 61**, wherein the step of implanting comprises implanting the member into pharyngeal region such that the member is substantially entirely submucosally implanted in the pharyngeal region.

13. **Claims 52-55** are rejected under 35 U.S.C. 102(a) and/or 102(e) as being anticipated by Doshi (US 2001/0052344 A1).

Regarding **claim 52**, Doshi disclose a method inherent in the use of an appliance **21**, the method comprising the steps of providing the appliance **21** in the oropharyngeal region of a human or animal, wherein the appliance **21** is located in the oropharyngeal region and is fully capable of being effective in treating at least one of sleep apnea and snoring during natural sleep of a human or animal.

Regarding **claim 53**, wherein the appliance **21**, when located in the oropharyngeal region, is fully capable of being effective in maintaining patency of the oropharyngeal region during natural sleep of a human or animal without causing substantial interference with at least one natural function of the epiglottis.

Regarding **claim 54**, wherein the step of providing the appliance **21** in which the appliance **21** is fully capable of being inserted into the oropharyngeal region while the appliance **21** is in a first configuration and allowing the appliance **21** to reconfigure to a second configuration within or in proximity to the oropharyngeal region.

Regarding **claim 55**, wherein the step of providing includes the appliance **21** in which the appliance **21** is fully capable of being inserted into the oropharyngeal region through a mouth of a person or animal.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. **Claims 6** and **30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al. (US 6,250,307 B1), as applied to **claims 1-5, 7-11, 13, 14, 16-29, 31-38** and **40-61** above. Conrad et al. teaches a device comprising all limitations recited in **claims 6** and **30**, but does not expressly disclose that the effective non-constrained

diameter is at least 32 mm or that the elongated member has a round cross-section. At the time of the invention was made, it would have been obvious to use an effective non-constrained diameter that is applicable to the size and shape of the patient's oropharyngeal passages. In addition, using a round cross-section, as opposed to a polygonal cross-section would have been obvious as well since these types of cross-sections are considered equivalents. Therefore, it would have been obvious to one having ordinary skill in the art to structure the appliance as Applicant has done. Moreover, Applicant has not asserted that the specific structural limitations recited provide a particular advantage, solve a stated problem or serve a purpose different from that of a different effective non-constrained diameter of about 20-30 mm (as disclosed by the prior art) or a rounded cross-section, thus the use of these structural elements lacks criticality in its utilization. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an effective non-constrained diameter of about 20-30 mm and a round cross-section. Therefore, it would have been obvious to modify the device of Conrad et al. by altering the structure to have the claimed details.

18. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al. (US 6,250,307 B1), as applied to **claims 1-5, 7-11, 13, 14, 16-29, 31-38** and **40-61** above, in view of Doshi (US 2001/0052344 A1). Conrad et al. discloses a device comprising all the limitations recited in **claim 15**, with the exception of a plurality of struts. However, the use of struts was known at the time the invention was made. Specifically, Doshi teaches the use of struts **20A, 20B, 20C, 20D** for providing support

in order to anchor the device during implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Conrad et al. by adding struts because it is well known in the art, as taught by Doshi, to add struts to in implantable medical device in order to anchor the device.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR 

January 21, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700